Application No.: 10/091,567 Docket No.: NEL-0006

## AMENDMENTS TO THE CLAIMS, COMPLETE LISTING OF CLAIMS IN ASCENDING ORDER WITH STATUS INDICATOR

Claims 1-19 (Canceled).

- 20. (Currently Amended) A [liposomal] <u>liposome-encapsulated plasmid DNA</u> vaccine composition comprising a plasmid encapsulated within a liposome, said plasmid <u>DNA</u> comprising a gene encoding for a hemagglutinin protein, wherein the liposome is prepared from a lipid film which is mixed with a solution containing said plasmid DNA.
- 21. (Previously Presented) The composition as claimed in claim 20, which is deliverable to a respiratory tract using intranasal administration and/or by aerosol inhalation.
- 22. (Previously Presented) The composition as claimed in claim 20, which prevents or treats an influenza virus infection.
- 23. (Currently Amended) The composition as claimed in claim 20, which elicits [long-lasting] <u>effective</u> protective antiviral immune responses against influenza viruses.
- 24. (Previously Presented) The composition as claimed in claim 20, wherein the plasmid is a plasmid vector construct pCI-HA10 which expresses said hemagglutinin protein in a host.
- 25. (Previously Presented) The composition as claimed in claim 20, wherein the plasmid and liposome are present in a concentration which ensures encapsulation of said plasmid in said liposome.
- 26. (Previously Presented) The composition as claimed in claim 20, wherein the concentration by weight of liposome is 25 times the concentration by weight of plasmid.

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27. (Previously Presented) The composition as claimed in claim 20, wherein said liposome comprises a formulation of 7% 1,2 dioleoyl-3-dimethylammonium chloride (DODAC), 78% 1,2-dioleoyl-sn-glycrerol-3-phospho-ethanolamine (DOPE) and 15% polyethylene glycol C8 ceramide (PEG<sub>2000</sub>C<sub>8</sub>CER).

- 28. (Currently Amended) A method of producing a liposomal vaccine composition, said method comprising:
- (1) preparing 7% DODAC, 78% DOPE, and 15% PEG<sub>2000</sub>C<sub>8</sub>CER at 10mg/ml concentrations to form a lipid film by drying at 50 °C for 2 hours under vacuum;
  - (2) incubating the lipid film at 50 °C for 2 hours under vacuum;
- (3) reconstituting the lipid film with distilled water and 1M  $\beta$ octylglucanopyranoside detergent at 20% of the total preparation volume;
- (4) adding a plasmid DNA to the lipid film at a concentration of 400  $\mu$ g DNA/ml to 10 mg/ml of lipid mixture solution, said plasmid comprising a gene encoding for a hemagglutinin protein;
- (5) transferring the reconstituted preparation into dialysis tubing and dialyzing in 1X HEPES buffer solution (150 mM NaCl, 20 mM Hepes, pH 7.4) at 23 °C for 15 hours; and
- (6) removing the free, non-encapsulate plasmid DNA from encapsulated plasmid DNA on a DEAE Sepharose CL-6B anion exchange column to obtain the liposomal vaccine composition comprising the liposome-encapsulated plasmid DNA [within the liposome].
- 29. (Previously Presented) A method for preventing and/or treating influenza virus infection, comprising administering to a patient in need thereof a pharmaceutically effective amount of the composition of claim 20.
- 30. (Previously Presented) The method as claimed in claim 29, wherein the composition is administered to a respiratory tract using intranasal administration, and/or aerosol inhalation.

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31. (Currently Amended) A method for eliciting [long-lasting] <u>effective</u> protective antiviral immune responses against influenza viruses, comprising administering to a patient in need thereof a pharmaceutically effective amount of the composition of claim 20.

32. (Previously Presented) The method as claimed in claim 31, wherein the composition is administered to a respiratory tract using intranasal administration, and/or aerosol inhalation.